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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,378	06/29/2006	Mark H Kaplan	50425/223	1608

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,378	KAPLAN, MARK H	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,13,16,19,20,22,24-27,34,35,41,72 and 119-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,13,16,19,20,22,24-27,34,35,41,72 and 119-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Claims 1-2, 13, 16, 19-20, 22, 24-27, 34-35, 41, 72, 119-123 are pending Claims 3-12, 14-15, 17-18, 21, 23, 28-33, 36-40, 42-71, 73-118 are cancelled and new claims 119-123 are added. by Preliminary Amendment filed on June 29, 2006.

Priority

2. This application filed on June 29, 2006 is a 371 of PCT/US03/37200 filed on 11/21/2003, which claims benefit of 60/428,335 file on 11/22/2002.

Information Disclosure Statement

3 The Information Disclosure Statement filed on June 29, 2006 has been considered.

Informalities

4. The following informalities are noted:

(i) the instant specification contains a list of references cited on page 1-7. It is advised that the placement of the references be at the end of the specification.

(ii) the sequence listing is in continuation with the instant specification on page 53-71. It is advised to provide the sequence listing on separate papers, not in continuation of the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 13, 16, 19-20, 22, 24-27, 34-35, 72, 119-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al. (Oncogene, Vol. 14 (13), pp. 1617-1622, 1997).

With regard to claims 1, 2, 16, 19-20, 34-35, 119, Lee et al. teach an isolated cDNA, a vector, and a cell comprising a fragment of at least 20 nucleotides comprising at least about 80% -90% homologous to SEQ ID No. 10 and at least a portion of SEQ ID No. 13, 11 and 15 (see sequence alignment from GenEmbl database showing 100% sequence similarity to the SEQ ID No. 10, and at least 10 contiguous nucleotides or portion of SEQ ID Nos. 11, 13, and 15 the sequences comprising said claimed SEQ ID No. 10, 11, 13 and 15 inherently comprises ELF3 gene introns since the sequence in the patent has homology (as recited in the claims a portion or at least 20 contiguous nucleotides or 80-90%) to the claimed sequences according to MPEP 2112"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

With regard to clams 22, 24-27, Chang et al. teach that the isolated cDNA is prepared from a cell obtained from a human patient being at risk for breast cancer, and the cells are taken from peripheral blood or tissue biopsy (see page 1621, Fig.3).

With regard to claims 72, 121-123, Chang et al. teach a probe homologous to the SEQ ID No. 10 as claimed comprising a detectable label (see page 1620, Fig.2). Accordingly the instant claims are anticipated by Chang et al.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (Oncogene, Vol. 14(13), pp. 1617-1622, 1997) in view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 17571761, 1990).

Chang et al. teach an isolated cDNA of mammalian ELF3 gene as discussed above in section 5.

However Chang et al. did not specifically teach a set of primers that are capable of directing synthesis of cDNA.

Lowe et al. teach a method for designing primers and evaluating their performance wherein Lowe et al. disclose a computer program for rapid selection of oligonucleotide primers for polymerase chain reaction (see page 1757, col. 1, abstract). Lowe et al. teach that all primers designed for over 10 gene products were experimentally tested and the results shoed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probes (see page 1760, col. 2, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the cDNA as taught by Chang et al. with a step of generate primers and designing primers to direct the synthesis of cDNA. It is also known (as taught by Lowe et al.) to design specific primers using computer program based on known sequences. An ordinary artisan would have had a reasonable expectation of success that such primers generated using known sequences as taught by Chang et al. in combination with the teachings of Lowe et al. to direct the synthesis of cDNA because the claimed primers are functional equivalents of the known sequences as taught by Chang et al. because Lowe e t al. explicitly taught designing and generating primers and probes from known sequences (see page 1760, col. 2, paragraph 1) and generating such primers and primer pairs are considered functionally equivalent to the claimed primers and primer pairs in the absence of secondary considerations. Further, selection of specific oligonucleotides for specific Tm represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Lowe et al. (This clearly shows that every primer would have a

reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe or primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims 1-2, 13, 16, 19-20, 22, 24-27, 34-25, 41, 72, 119-123 drawn to an isolated cDNA and its portions or fragments or variants of at least 20 nucleotides (by substitution, deletion, insertion), comprising at least 80-90% homology to SEQ ID No. 10, 11, 13,and 15. This large genus of fragments and variants is represented in the specification by the named SEQ ID No. 10, 11, 13, and 15. Thus applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements

possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the sequences are disclosed in the sequences (i) with said fragements (ii) variants of said polynucleotide obtained by substitution, deletion, or insertion comprising the 80-90% homology. With regard to the sequences comprising fragments represented by at least 80-90% homology or fragments having at least 20 nucleotides long, this is insufficient to demonstrate identity of biological and binding function where no structural information regarding where in the polynucleotide fragment the biological function resides. Further no structural information regarding the coding region of the said polynucleotide. Further no information is given regarding a methodology to determine such common elements or attributes. Further, there is no description of fragments or variants.

With regard to the written description, all of these claims encompass nucleic acid sequences different from the disclosed in the specific 10, 11, 13, and 15, which include modifications by permitted by fragments and variants, for which no written description is provided in the specification. It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any amino acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos. retaining correlative function in the claimed product.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner,
Art Unit 1637

Prabha Chunduru 6/25/07
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